

Express Mail No. E1467873195US

Docket No. PC7558D
Applicant: Robert N. Hamlin
Serial No.: 08/692,314

--158. (New) The method of claim 152 wherein the second parison layer consists essentially of polyvinyl chloride.--

--159. (New) The method of claim 152 wherein the second parison layer consists essentially of polyurethane.--

--160. (New) The method of claim 152 wherein the first balloon layer is an outermost balloon layer.--

--161. (New) The method of claim 152 wherein the second balloon layer is an innermost balloon layer.--

--162. (New) The method of claim 152 further comprising applying a lubricious coating on an outermost balloon layer.--

--163. (New) The method of claim 152 wherein the polyethylene terephthalate of the first parison layer has a higher crystallinity than the polymeric material of the second parison layer.--

--164. (New) The method of claim 152 wherein the second parison layer consists essentially of polyester other than polyethylene terephthalate.--

--165. (New) The method of claim 152 wherein the parison is first longitudinally drawn and then radially expanded.--

REMARKS

An Office Action was mailed November 13, 1996 (paper no. 23). Applicant filed an Amendment and Supplemental Information Disclosure Statement on April 14, 1997 pursuant to 37 C.F.R. § 1.8. A Communication was mailed on May 19, 1997 (paper no. 28). After the Communication was mailed, but before the Communication was received, Applicant filed a Supplement to Amendment and Second Supplemental Information Disclosure Statement on May 20, 1997 pursuant to 37 C.F.R. § 1.10. This "Amendment in Response to

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"Communication" is submitted to fully address all of the issues presented in the Communication.

Applicant acknowledges that the Examiner has deemed claims 94-115 drawn to a balloon (Group I) to be distinct from cancelled claims 61-64, 74-76, 79, 80; and 83-93 drawn to a method of making a balloon¹ (Group II), and has withdrawn claims 94-115 from consideration. Applicant's Amendment mailed April 14, 1997, was deemed to be drawn to a constructively non-elected invention and was therefore deemed to be non-responsive.

The undersigned wishes to assure Examiner Maki that the Amendment dated April 14, 1997 and the Supplement to Amendment filed May 20, 1997 were both filed in an effort to fully respond to the Office Action mailed November 13, 1996. Nonetheless, in an effort to expedite examination and allowance of this application, Applicant has cancelled claims 94-115 without prejudice or disclaimer and has substituted claims 116-165 therefor. New claims 116-165 are directed to methods of making a balloon. (Applicant intends to prosecute claims directed to balloons by way of a divisional application pursuant to 35 U.S.C. § 121.)

Applicant respectfully submits that support is found for new claims 116-165 in applicant's patent application serial no. 07/411,649, filed September 25, 1989 and Applicant's patent application serial no. 07/727,664, filed July 9, 1991, *inter alia*, as indicated in the following table:

¹ Group II claims are described alternately as an "attaching method" (paper no. 28, page 1, lines 20-21) and a "process of making" (paper no. 28, page 1, line 25). Applicant submits that the description of the claims of Group II as a "process of making" is more accurate.

Claim No.	Claim Recitation	Support in 07/411,649	Support in 077727,664
116	<p>A method of making a coronary angioplasty catheter balloon, the method comprising:</p> <p>(a) co-extruding a tube having a first tube layer comprising a first polymeric material and a second tube layer comprising a second polymeric material which is different than the first polymeric material; and</p> <p>(b) longitudinally drawing and radially expanding the tube to make a resulting balloon which is sized and configured for intravascular coronary angioplasty use with a burst pressure in excess of seven atmospheres, the balloon having a first balloon layer comprising the first polymeric material and a second balloon layer comprising the second polymeric material, one of the first and second balloon layers being less compliant than the other layer.</p>	<p>p. 1, line 10; p. 2, line 23 - p. 3, line 10; p. 4, lines 11-15; p. 5, lines 4-26; p. 6, lines 3-6; p. 8, claim 9.</p> <p>p. 3, lines 5-8.</p>	<p>p. 1, lines 32-33; p. 4, line 22 - p. 5, line 3; p. 6, line 14 - p. 7, line 37; p. 9, lines 21-32.</p> <p>p. 4, line 34 - p. 5, line 3.</p>
117,	... wherein the first balloon layer is less compliant than the second balloon layer.		
135	... the first tube, parison layer comprises polyester.		<p>p. 7, lines 3-10; p. 8, claim 9.</p>
118,			<p>p. 9, lines 21-32.</p>
136	... wherein the first tube, parison layer consists essentially of polyethylene terephthalate co-polyester, or	<p>p. 8, claim 2.</p>	<p>p. 13, claim 14.</p>
119,	... wherein the first tube, parison layer consists essentially of polyethylene terephthalate homopolyester.		<p>p. 5, lines 23-24.</p>
137,			<p>p. 13, claim 14.</p>
153	... wherein the first tube, parison layer consists essentially of polyethylene terephthalate homopolyester.		
120,	... wherein the first tube, parison layer consists essentially of polyethylene terephthalate co-polyester.	<p>p. 8, claim 2.</p>	<p>p. 13, claim 14.</p>
138,			
154	... wherein the first tube, parison layer consists essentially of polyethylene terephthalate co-polyester.		
121,	... wherein the second tube, parison layer consists essentially of polyolefin.	<p>p. 5, line 22.</p>	<p>p. 4, line 6.</p>
139,			
155	... wherein the second tube, parison layer consists essentially of polyethylene.	<p>p. 9, claim 10.</p>	<p>p. 4, line 6.</p>
122,			
140,			
156			
123,	... wherein the second tube, parison layer consists essentially of polyethylene.		
141,			
157			
124,	... wherein the second tube, parison layer consists essentially of polyvinyl chloride.	<p>p. 6, line 18.</p>	<p>p. 4, line 7.</p>
142,			
158	... wherein the second tube, parison layer consists essentially of polyurethane.	<p>p. 9, claim 10.</p>	<p>p. 4, line 7.</p>
125,			
143,			
159	... wherein the first balloon layer is an innermost balloon layer.		<p>p. 7, lines 3-10.</p>
126,			<p>p. 9, lines 21-32.</p>
144	... wherein the first balloon layer is an outermost balloon layer.		<p>p. 7, lines 24-26.</p>
145,			
160			

Claim No.	Claim Recitation	Support in 07/411,649	Support in 07/727,664
128,	... wherein the second balloon layer is an innermost balloon layer.	p. 7, lines 3-10.	p. 9, lines 21-32.
146,			
161			
129,	... wherein the second balloon layer is an innermost balloon layer.	p. 5, lines 25-26.	p. 7, lines 24-26.
147			
130,	... further comprising applying a lubricious coating on an outermost balloon layer.	p. 3, lines 11-15.	p. 5, lines 4-10
148,			
162			
131,	... wherein the polyester, PET of the first tube, parison layer has a higher crystallinity than the polymeric material of the second tube, parison layer.	p. 7, lines 3-10.	p. 2, lines 30-31.
149,			
163			
132,	... wherein the second tube, parison layer consists essentially of polyester, PET other than the polyester, PET of the first tube, parison layer.	p. 7, lines 3-10 & p. 9, lines 21-32	p. 9, lines 21-32
150,			
164			
133,	... wherein the tube, parison is first longitudinally drawn and then radially expanded.	p. 6, lines 13-14.	p. 9, lines 36-37.
151,			
165			
134	A method of making a coronary angioplasty catheter balloon, the method comprising:	p. 1, line 10; p. 2, line 23 - p. 3, line 10; p. 4, lines 11-15; p. 5, lines 4-26; p. 6, lines 3-6; p. 7, line 7; p. 9, lines 21-32.	p. 1, lines 32-33; p. 4, line 22 - p. 5, line 3; p. 6, line 14 - p. 7, line 7; p. 9, lines 21-32.
	(a) co-extruding a parison having a first parison layer comprising a first polymeric material and a second parison layer comprising a second polymeric material which is different than the first polymeric material;		
	(b) disposing the parison in a mold; and		
	(c) heating, longitudinally drawing, and radially expanding the parison to make a resulting balloon which is sized and configured for intravascular coronary angioplasty use with a burst pressure in excess of seven atmospheres, the balloon having a first balloon layer comprising the first polymeric material and a second balloon layer comprising the second polymeric material, one of the first and second balloon layers being less compliant than the other layer.		
152	A method of making a coronary angioplasty catheter balloon, the method comprising:	p. 1, line 10; p. 2, line 23 - p. 3, line 10; p. 4, lines 11-15; p. 5, lines 4-26; p. 5, lines 23-24; p. 6, lines 3-6; p. 6, lines 13-16; p. 7, lines 3-10; p. 8, claim 2; p. 8, claim 9.	p. 1, lines 32-33; p. 4, line 22 - p. 5, line 3; p. 6, line 14 - p. 7, line 37; p. 8, lines 36 - p. 9, line 3; p. 9, lines 21-32; p. 13, claim 14.
	(a) co-extruding a parison having a first parison layer consisting essentially of polyethylene terephthalate;		
	(b) disposing the parison in a mold; and		
	(c) heating, longitudinally drawing, and radially expanding the parison to make a resulting balloon which is sized and configured for intravascular coronary angioplasty use with a burst pressure in excess of seven atmospheres, the balloon having a first balloon layer consisting essentially of biaxially oriented polyethylene terephthalate and a second balloon layer consisting essentially of the material which is different than polyethylene terephthalate, the first balloon layer being less compliant than the second balloon layer.		

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Applicant respectfully submits that no new matter has been added by way of the new claims.

The objection to the specification and rejection of claims 74-76, 79, 83-85, and 90-93 under 35 U.S.C. § 112, first paragraph, have been rendered moot by the cancellation of the rejected claims. (Nonetheless, applicant respectfully points out that biaxial orientation of the multilayer balloon is supported in the original specification, e.g., at page 4, lines 5-7 and at page 5, line 21 - page 6, line 27.) Accordingly, withdrawal of the objection and rejection is respectfully requested.

Claims 61-64, 74-76, 79, 80, and 83-93 had been rejected over Wang et al. (U.S. Patent No. 5,195,969) in view of several secondary documents. These rejections have been rendered moot by the cancellation of said claims and the substitution of claims 116-165 therefor. Accordingly, withdrawal of these rejections is respectfully requested.

Claims 61-64, 74-76, 79, 80, and 82-93 had also been rejected over Levy (U.S. Patent No. 4,490,421) in view of numerous secondary documents. These rejections have also been rendered moot by the cancellation of said claims and the substitution of claims 116-165 therefor. Accordingly, withdrawal of these rejections is respectfully requested.

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Applicant respectfully submits that the cited documents, either alone or in combination, do not teach or suggest the invention as claimed in new claims 116-165. The new claims have an effective filing date of September 25, 1989, which predates the Wang et al. patent filing date, and Levy does not teach or suggest a method of making a catheter balloon comprising, *inter alia*, co-extruding a tube having a first layer comprising a first polymeric material and a second layer comprising a second polymeric material which is different than the first polymeric material.

The undersigned respectfully requests an interview with the Examiner to discuss the foregoing amendments and remarks in person before the issuance of further papers in this application. I will telephone Examiner Maki within the next week to schedule an interview.

Applicant respectfully submits that the claims are in condition for allowance. Such favorable action is earnestly solicited.

Respectfully submitted,



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Date: June 18, 1997
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